

Claims 4 stand rejected under 35 USC 112 as being indefinite, the Examiner having singled out the phrase "including". It is believed the above amendments deleting such language from claim 4 has obviated the rejection, and withdrawal of the rejection is accordingly respectfully requested.

Claims 1-7 stand rejected under 35 USC 103(a) as being unpatentable over Bailey et al. (Lancet) or Thylefors (Who Drug Information) in combination with Hauske (US 4,512,982) and Kruse (US 5,646,151). The Examiner stated that the primary references disclose the use of azithromycin for the treatment of eye infections by other than a topical route, and that the secondary references demonstrate that topical administration of azithromycin was well known. The Examiner took the position that a person ordinarily skilled in the art would have been motivated to prepare topical compositions containing azithromycin and administer the same topically to the eye in order to treat eye infections.

The rejection is traversed on the basis that the combinations of references cited by the Examiner would not suggest or motivate making a topical composition comprising azithromycin adapted for topical administration to the eye.

The primary references, Bailey and Thylefors, do indeed disclose or suggest azithromycin for the treatment of trachoma. No disclosure or even a remote suggestion of topical administration is made, however.

So far as the secondary references are concerned, Hauske does not suggest topical administration of azithromycin to the eye. Indeed the sentence prior to the section cited by the Examiner discloses that:

"Their in vitro activity renders them useful for topical application; for sterilization purposes, e.g., sick-room utensils; and as industrial microbials, for example, in water treatment, slime control, paint and wood preservation." [Hauske at Column 9, lines 20-24]

Clearly, one skilled in the art would not view Hauske as suggesting topical administration to the eye. Further, although Hauske does relate to macrolide antibiotics and/or derivatives related to azithromycin, it does not relate to azithromycin per se. In column 2 of Hauske, formula (III) differs from azithromycin at least insofar as the substitution at the 4" on the lower (cladinose) sugar ring is concerned. Formula (IV) also differs at the same position. Kruse relates to kappa opioid receptor agonist compounds having different structures from macrolides, not to mention different utilities. It is respectfully submitted that one skilled in the art interested in topical formulations of any kind of macrolide would undoubtedly dismiss Kruse out of hand as irrelevant.

It is accordingly respectfully requested that the rejection under 35 USC 103 be withdrawn.

Claims 4-7 stand rejected under 35 USC 102(a) as being anticipated by Bailey, Thylefors, or Hauske. The rejection is traversed since none of the references in fact disclose an azithromycin composition adapted for topical application to the eye. Applicants' arguments from above are incorporated by reference in this respect. As noted above, Hauske does not disclose any topical application for the eye, but rather simply alludes to topical application for utilities such as instrument sterilization and slime control. Kruse does not relate to azithromycin at all that Applicant can see. Bailey mentions the administration

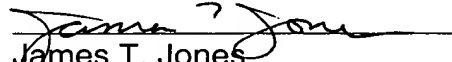
of azithromycin only in the context of oral administration as a suspension. No azithromycin compositions for topical administration to the eye is disclosed in any of these documents.

It is accordingly respectfully requested that the rejection under 35 USC 102 be withdrawn.

In view of the foregoing comments and amendments, a Notice of Allowance is courteously solicited.

Respectfully submitted,

Date: MARCH 10, 2000


James T. Jones
Attorney for Applicant
Reg. No. 30,561

Pfizer Inc
Patent Department
Eastern Point Road
Groton, CT 06340
(860) 441-4903